

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SAN ROCCO THERAPEUTICS, LLC,

Plaintiff,

v.

BLUEBIRD BIO, INC. and
THIRD ROCK VENTURES, LLC,

Defendants.

C.A. No. 21-1478-RGA-JLH

PUBLIC VERSION

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**DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR
MOTION TO DISMISS THE SECOND AMENDED COMPLAINT OR,
ALTERNATIVELY, TO COMPEL ARBITRATION AND STAY THE PROCEEDINGS**

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I. **NATURE AND STAGE OF PROCEEDINGS**

Defendants bluebird bio, Inc. (“bluebird”) and Third Rock Ventures, LLC (“Third Rock,” and, together with bluebird, “Defendants”) move pursuant to Rules 12(b)(1) and (6) of the Federal Rules of Civil Procedure to dismiss all claims brought by Plaintiff San Rocco Therapeutics, LLC (“Plaintiff” or “SRT”) in its Second Amended and Supplemental Complaint for Patent Infringement filed on March 7, 2022 (D.I. 39) (“the Second Amended Complaint”). In the alternative, Defendants move for an order compelling arbitration and staying these proceedings pursuant to Sections 3 and 4 of the Federal Arbitration Act, 9 U.S.C. § 1 *et seq.* (“the FAA”). This is Defendants’ Opening Brief in support of that motion.

II. **SUMMARY OF ARGUMENT**

Despite twice amending its pleading, SRT has failed to establish standing to sue for patent infringement. In both SRT’s original Complaint filed on October 21, 2021 (D.I. 1) and its first Amended Complaint filed on November 17, 2021 (D.I. 9), SRT alleged standing based upon license rights conferred in an agreement that SRT failed to disclose was long ago terminated.¹ Accordingly, Defendants filed a motion to dismiss on January 14, 2022 (D.I. 16), on various grounds including for lack of standing. In response, SRT sought leave to file the Second Amended Complaint. (D.I. 39.) Defendants did not oppose this request, even though the amendment failed to cure any defect.

¹ Specifically, SRT relied upon a March 7, 2005 license agreement (“the 2005 License Agreement,” attached as Exhibit A) between SRT and non-party Sloan-Kettering Institute for Cancer Research (“SKI”), which is an affiliate of the assignee of the patents-in-suit, non-party Memorial Sloan Kettering Cancer Center (“MSK,” and, together with SKI, “MSK/SKI”). SRT and MSK/SKI terminated the 2005 License Agreement pursuant to a June 17, 2011 agreement (“the 2011 Termination Agreement,” attached as Exhibit B). The Court may consider these documents on this Rule 12 motion because they are “integral to” and “expressly relied upon” in the Second Amended Complaint. *Lum v. Bank of Am.*, 361 F.3d 217, 221-22 n.3 (3d Cir. 2004).

In the Second Amended Complaint, SRT now alleges that it has standing to sue based upon rights conferred pursuant to a November 2, 2020 Settlement Agreement (“the 2020 Settlement Agreement,” attached as Exhibit C). The 2020 Settlement Agreement, which SRT did not even mention in the first two complaints, settled a long-running dispute among the parties (and non-party MSK/SKI) litigated in New York and Massachusetts state courts for several years. The 2020 Settlement Agreement contains only a single-sentence license provision, which states:

[REDACTED] (Id. § 2.) Such a bare license is insufficient to confer standing under Article III of the Constitution (*see infra* IV.A) and statutory standing under 35 U.S.C. § 281 (*see infra* IV.B). Accordingly, the Court should dismiss this case with prejudice for lack of standing.

In any event, the 2020 Settlement Agreement bars SRT’s claims. Pursuant to the 2020 Settlement Agreement, the parties exchanged broad “mutual general releases,” including to “all claims . . . accrued or unaccrued” that “relate to or arise out of,” *inter alia*, the “Dispute,” defined as “any and all disputes related to the 2005 [License] Agreement, the 2011 [Termination] Agreement, the New York Litigation and the Massachusetts Litigation.” (Ex. C at preamble, § 5.) SRT’s claims in this lawsuit for alleged patent infringement relate to and arise out of the very same agreements, and the very same gene therapy treatment developed by bluebird, at issue in the prior litigations.²

² The Court may take judicial notice of the allegations in these litigations and their relationship to the allegations in this lawsuit, as matters of public record, *see, Acierno v. Haggerty*, No. 04-1376-KAJ, 2005 WL 3134060, at *5-6 (D. Del. Nov. 23, 2005), and because SRT “explicitly relied upon” the operative complaints in these litigations in the Second Amended Complaint, *Lum v. Bank of Am.*, 361 F.3d 217, 221-22 n.3 (3d Cir. 2004).

SRT (as well as the assignee and licensor, MSK/SKI) also provided a further broad release to Defendants in the 2020 Settlement Agreement, which “fully, finally and forever” releases them of “any and all claims” that SRT (as well as MSK/SKI) “may have, ever had or now has” against them. (Ex. C, § 5.) The phrase “may have” is future-oriented, and thus further releases any and all claims that accrued after the 2020 Settlement Agreement “for upon or by reason of any cause or thing” that happened previously. (*See infra* IV.C.) This includes bluebird’s continued use of a lentiviral vector in the gene therapy treatment that SRT claims to be an “Infringing Drug Product.” (D.I. 39, ¶ 5.) Accordingly, the releases in the 2020 Settlement Agreement bar this lawsuit. (*See infra* IV.C.) As discussed further below, MSK/SKI—which is both a party to the 2020 Settlement Agreement and the licensor of alleged patent rights upon which SRT now relies for standing—agrees with Defendants.

Alternatively, if the Court does not dismiss this lawsuit and if SRT presents a legitimate dispute concerning the construction of the license rights and releases in the 2020 Settlement Agreement, the Court should stay these proceedings and compel arbitration. The 2020 Settlement Agreement contains a broad dispute resolution provision, which states that any dispute “concerning” the 2020 Settlement Agreement or “its construction” that the parties cannot amicably resolve shall be arbitrated before David Ichel of X-Dispute, LLC. (Ex. C, § 7.)³ Thus, in the event of any such legitimate dispute, an arbitration would be necessary to resolve threshold issues before any alleged infringement claims could proceed. (*See infra* IV.D.)⁴

³ To the extent Mr. Ichel is not available, any dispute would be heard by “three (3) neutral arbitrators . . . seated in New York, New York under the AAA Arbitration Rules.” (Ex. C, § 7.)

⁴ Defendants deny any alleged infringement of the patents-in-suit (either direct or induced), and are prepared to demonstrate that there is no basis for any claims of infringement. This issue, however, is not pertinent to this motion.

III. STATEMENT OF FACTS

A. The Parties

Plaintiff SRT alleges that it is a biopharmaceutical company based in Tampa, Florida. (D.I. 39, ¶¶ 3, 7.) SRT purports to compete with bluebird regarding the development of recombinant vectors used in gene therapies to treat severe genetic diseases, such as transfusion-dependent β-thalassemia (“TDT”) and sickle cell disease (“SCD”). (*E.g.*, *id.* ¶¶ 4-6.)

Defendant bluebird is an established research-and-development-based biotechnology company headquartered in Cambridge, Massachusetts. It independently developed a lentiviral vector⁵ used to make gene therapies that treat TDT (betibeglogene autotemcel, or beti-cel) and SCD (lovotibeglogene autotemcel, or lovo-cel), which SRT alleges infringes the patents-in-suit. In June 2019, the European Commission conditionally authorized beti-cel for marketing under the brand name Zynteglo®. In September 2021, bluebird completed the submission of its Biologic License Application to the FDA seeking beti-cel approval in the United States, which it has not yet received. Lovo-cel is still under development in clinical trials.

Defendant Third Rock is a venture capital firm based in Boston, Massachusetts, and a past shareholder of bluebird. Third Rock does not currently own bluebird stock.

B. The Patents-in-Suit

The patents-in-suit are U.S. Patent Nos. 7,541,179 (“the ’179 patent”) and 8,058,061 (“the ’061 patent”). They share a specification and purport to claim priority to the same provisional applications filed in mid-2001. They reflect work done more than two decades ago

⁵ SRT refers to this vector in the Second Amended Complaint as the “BB305 vector.” (D.I. 39, ¶ 5.)

by scientists at non-party MSK—not SRT. MSK, which is not a party to this lawsuit, is the assignee of the patents-in-suit. (D.I. 39, ¶¶ 14-17.) Both patents are fast-approaching expiration.

On March 17, 2005, SRT and MSK (through its affiliate, SKI) entered into the 2005 License Agreement, which granted an “exclusive worldwide right and license” to SRT to “commercially develop” a drug product practicing the patents-in-suit. (Ex. A at preamble, § 2.1.) On June 17, 2011, SRT and MSK, through SKI, executed the 2011 Termination Agreement, which terminated the 2005 License Agreement and all of SRT’s rights to practice the patents-in-suit. (See Ex. B.) Although the Amended Complaint is replete with allegations that Defendants infringed SRT’s alleged patent rights during the decade that followed (see, e.g., D.I. 39, ¶¶ 112-14, 120, 131), SRT has no basis to contend that it had any rights to the patents-in-suit from June 17, 2011, through at least November 2, 2020.

C. The 2020 Settlement Agreement

In 2017, SRT sued bluebird and SKI in the Supreme Court of the State of New York, in an action captioned *Errant Gene Therapeutics, LLC v. Sloan-Kettering Institute for Cancer Research*, No. 150865/2017 (“the New York Litigation”). In 2019, SRT filed a related lawsuit against Third Rock and an individual defendant in the Superior Court in the Commonwealth of Massachusetts, in an action captioned *Errant Gene Therapeutics, LLC v. Third Rock Ventures, LLC*, No. 19-1832 (“the Massachusetts Litigation”). The central issue in both litigations concerned bluebird’s gene therapies using the BB305 vector, which is the allegedly infringing drug product at issue in this lawsuit, and its purported competition with SRT’s alleged developmental gene therapy. (See, e.g., Ex. D, ¶¶ 48-55, 169-176, 292-315; Ex. E, ¶¶ 1-3, 33-37, 57-67.)

A trial began in New York on October 29, 2020. On November 2, 2020, before the end of trial, SRT, MSK/SKI, and bluebird entered into the 2020 Settlement Agreement, which settled

both the New York Litigation and the Massachusetts Litigation. (Ex. C at preamble.)⁶ The 2020 Settlement Agreement reiterates that the 2005 License Agreement is “terminated.” (*Id.* § 4.)

1. The One-Sentence License Provision

The 2020 Settlement Agreement contains a one-sentence license provision relevant to the patents-in-suit: [REDACTED]

[REDACTED]
[REDACTED] (*Id.* § 2.) As such, the 2020 Settlement Agreement conveyed to SRT neither exclusionary rights in, nor all substantial rights to, the patents-in-suit. Moreover, Defendants are not aware of any subsequent agreement actually [REDACTED] any such rights, or otherwise relating to any such rights to the patents-in-suit. Nor is any allegation of such an agreement in the Second Amended Complaint. Accordingly, SRT does not have constitutional or statutory standing, as discussed in Sections IV.A and IV.B below, respectively.

2. The Broad Releases

The 2020 Settlement Agreement contains several relevant releases. First, the parties exchanged a broad, mutual and general release as follows:

The Parties exchange mutual general releases which shall include, without limitation, all claims, both at law and in equity, accrued or unaccrued, known or unknown, suspected or unsuspected that relate to or arise out of (i) the 2005 [License] Agreement, (ii) the 2011 [Termination] Agreement, (iii) the Dispute, (iv) the action of any of the Parties or any Affiliate of any Party leading to the execution of the 2005 Agreement or the 2011 Agreement, including any costs, expenses and legal fees.

⁶ Although Third Rock is not a signatory to the 2020 Settlement Agreement, the agreement settled and released all claims against Third Rock in the Massachusetts Litigation, and Third Rock was included in the definition of “BBB Releasees,” as a “past . . . shareholder[]” of bluebird. (*Id.* § 5.)

(Ex. C, § 5.) The “Dispute” is defined as “any and all disputes related to the 2005 [License] Agreement, the 2011 [Termination] Agreement, the New York Litigation and the Massachusetts Litigation.” (*Id.* at preamble.)

SRT additionally provided a further release to Defendants:

[SRT] Releasees⁷ fully, finally and forever release, relinquish, acquit and discharge [bluebird] and all of [bluebird’s] past and present partners and associates, principals, shareholders, members, directors, officers, representatives, predecessors, successors, partnerships, corporations, heirs, executors, administrators, assigns, insurers, reinsurers, employees and attorneys (collectively the “BBB Releasees”) from and against any and all claims, causes of action, demands, disputes, suits, debts, dues, liabilities, sums of money, accounts, reckonings, specialties, bonds, covenants, contracts, agreements, controversies, promises, assessments, rights, damages, costs and/or expenses whether based on a tort, contract or any other theory of recovery, in law, admiralty or equity, whether known or unknown, suspected or unsuspected, asserted or unasserted, foreseen or unforeseen, that [SRT] Releasees may have, ever had or now has against the BBB Releasees or any of them, for upon or by reason of any cause or thing, from the beginning of the world to the Parties’ execution of this Confidential Settlement Agreement.

(*Id.* § 5.)

Likewise, MSK/SKI—the assignee and licensor of the patents-in-suit—provided a further, and substantively identical, release to Defendants:

MSK Releasees⁸ fully, finally and forever release, relinquish, acquit and discharge BBB’s Releasees from and against any and all claims, causes of action, demands, disputes, suits, debts, dues, liabilities, sums of money, accounts, reckonings, specialties, bonds, covenants, contracts, agreements, controversies, promises, assessments, rights, damages, costs and/or expenses whether based on a tort, contract or any other theory of recovery, in law, admiralty or equity, whether known or unknown, suspected or unsuspected, asserted or

⁷ “[SRT] Releasees” is defined in the 2020 Settlement Agreement as “[SRT], and each of its predecessors, successors, assigns, officers, directors, employees, trustees, attorneys, parents, subsidiaries and affiliates.” (*Id.*)

⁸ “MSK Releasees” is defined in the 2020 Settlement Agreement as “[MSK/SKI] and each of its predecessors, successors, assigns, officers, directors, employees, trustees, attorneys, parents, subsidiaries and affiliates.” (*Id.*)

unasserted, foreseen or unforeseen that MSK Releasees may have, ever had or now has against the BBB Releasees or any of them, for upon or by reason of any cause or thing, from the beginning of the world to the Parties' execution of this Confidential Settlement Agreement.

(*Id.*) As discussed below in Section IV.C, these broad releases bar SRT's claims in this lawsuit.

3. The Arbitration Agreement

Section 7 of the 2020 Settlement Agreement contains a dispute resolution provision, with an agreement to arbitrate:

The Parties shall make all reasonable efforts to resolve any dispute concerning this Confidential Settlement Agreement, its construction, or its actual or alleged breach, by face-to-face negotiations between senior executives. Should such negotiation fail to resolve the matter, as defined by either party sending written notice to the other party of an impasse after at least one face-to-face negotiation meeting among senior executives of the parties, the matter shall be finally decided by David Ichel of X-Dispute, LLC or, if Mr. Ichel is not available, three (3) neutral arbitrators (the "Tribunal") seated in New York, New York under the AAA Arbitration Rules (the "Rules").

(*Id.* § 7.) Accordingly, as discussed in Section IV.D below, in the event this Court does not dismiss this lawsuit outright, and in the event SRT raises any legitimate dispute as to the scope of the license rights or releases provided under the 2020 Settlement Agreement, such threshold issues should be resolved in arbitration.

D. Non-Party MSK/SKI, the Assignee and Licensor of the Patents-in-Suit, Confirms That SRT's Claims Are Improper and Lack Good Faith

On February 7, 2022, approximately three weeks after Defendants moved to dismiss SRT's first Amended Complaint, SRT emailed MSK/SKI through its outside counsel. (*See* Feb. 7-10, 2022 emails between SRT and MSK/SKI counsel, Ex. F.) SRT advised MSK/SKI of its patent infringement claims in this lawsuit and Defendants' motion to dismiss, including for lack of standing. (*Id.*) SRT asked MSK/SKI to state its position as to whether MSK/SKI—as the

assignee and licensor of the patents-in-suit—is a “necessary party” to this lawsuit under Rule 19 of the Federal Rules of Civil Procedure. (*Id.*) In response, MSK/SKI took “no position” at that time and reserved all rights because, *inter alia*, it had not been “named” in, or “served” with, any pleading in connection with this lawsuit. (*Id.*). MSK/SKI stated, however, that this lawsuit “is improper, at least because the claims were released by the 2020 [Settlement] [A]greement,” to which MSK/SKI is a party, and because the parties to the 2020 Settlement Agreement “agreed to submit any dispute relating to [it] to arbitration.” (*Id.*) MSK/SKI also stated that it “will not join [SRT’s] complaint as a co-plaintiff because [MSK/SKI] does not believe there is a good-faith basis for [SRT’s] claims.” (*Id.*)

IV. ARGUMENT

A. SRT Lacks Constitutional Standing

Standing is “an essential and unchanging part” of the case-or-controversy requirement of Article III of the United States Constitution. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). “In reviewing a factual challenge to the Court’s subject matter jurisdiction” for lack of standing, “the Court is not confined to the allegations of the Complaint, and the presumption of truthfulness does not attach to the allegations in the complaint.” *Palamarachouk v. Chertoff*, 568 F. Supp. 2d 460, 464 (D. Del. 2008). In a patent infringement case, when the Court’s subject matter jurisdiction is challenged pursuant to Rule 12(b)(1) for lack of standing, the plaintiff “has the burden to show” the necessary rights to support its standing to sue under the patents-in-suit. *Abbott Point of Care Inc. v. Epocal, Inc.*, 666 F.3d 1299, 1302 (Fed. Cir. 2012).

Constitutional standing in a patent infringement case “does not depend on labels.” *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp. USA*, 925 F.3d 1225, 1234 (Fed. Cir. 2019). Nor “does [it] turn” on whether a plaintiff is alleged to be an “exclusive licensee.” *Uniloc USA, Inc. v. Motorola Mobility, LLC*, No. 17-1658-CFC, 2020 WL 7771219, at *5 (D. Del. Dec. 30,

2020) (appeal pending). “If [a licensee] has not received . . . the right to exclude others from making, using, or selling the patented invention, the party has a ‘bare license,’ and has received only the patentee’s promise that that party will not be sued for infringement.” *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995) (en banc); *see also In re Cirba Inc.*, No. 2021-154-LPS, 2021 WL 4302979, at *2 (Fed. Cir. Sept. 22, 2021) (non-precedential) (to establish constitutional standing, the plaintiff must have “the right to exclude others from using the patented invention”); *Lone Star*, 925 F.3d at 1234-36 (stating that “exclusionary rights” are required for constitutional standing).

SRT’s Second Amended Complaint now relies solely upon the 2020 Settlement Agreement as allegedly conferring standing. The 2020 Settlement Agreement, however, contains merely a one-sentence license provision stating that MSK [REDACTED]

[REDACTED]
[REDACTED] (Ex. C, § 2.) Even putting aside that an agreement to provide license rights is not a license itself, *cf. Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000) (explaining that “an *agreement to assign*” is “not an assignment”), this provision could not be any more bare bones. And although the 2020 Settlement Agreement uses the term [REDACTED]

[REDACTED]
[REDACTED]
(Ex. C, § 2.)

As noted above, the Federal Circuit has made clear that the use of the word “[REDACTED]” is not controlling; what matters is whether the plaintiff has “the right to exclude others from using the patented invention.” *Cirba*, 2021 WL 4302979, at *2; *see also Uniloc*, 2020 WL 7771219, at *5. Here, the 2020 Settlement Agreement does not provide SRT with any right to exclude others

from practicing the patents-in-suit. Nor does it provide SRT the power to police infringement of the patents-in-suit. Nor to license or sublicense any rights to the patents-in-suit. Nor to forgive activity otherwise prohibited under the patent statutes. This is plainly insufficient.

SRT alleges, without any support, that the one-sentence license provision in the 2020 Settlement Agreement grants SRT “the right to exclude others from making, having made, using, importing, selling, or offering for sale in the United States any lentiviral vector, gene therapy treatment, or drug product that is covered by a valid claim of the Patents-in-Suit, which are the intellectual property licensed in the 2005 Agreement.” (D.I. 39, ¶¶ 19-20, 24-34.) SRT also alleges, without any support, that MSK “did not retain any rights” to the patents-in-suit, that SRT is “able to commence an action for infringement,” and that SRT has “the primary responsibility for enforcing” the patents. (*Id.*, ¶¶ 35-38, 41-24.)⁹

The 2020 Settlement Agreement does not support these allegations, and SRT’s bald allegations otherwise are insufficient to meet SRT’s burden to demonstrate constitutional standing. *See, e.g., Palamarachouk*, 568 F. Supp. 2d at 464 (allegations alone are insufficient to establish standing in response to motion under Rule 12(b)(1)); *Abbott Point of Care Inc.*, 666 F.3d at 1302 (plaintiff “has the burden to show,” not merely allege, “necessary ownership rights to support standing to sue” for infringement); *Uniloc*, 2020 WL 7771219, at *5 (“the touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right in a patent,” as opposed to merely alleging it has this right) (internal quotations and emphasis omitted); *Cirba*, 2021 WL 4302979, at *4 (finding lack of

⁹ Even under its incorrect and unsupported interpretation of the 2020 Settlement Agreement, SRT recognizes that there are limitations on its rights. For example, SRT concedes that it is able to commence an action for infringement only “when the patent owner refuses to vindicate [SRT’s] right.” (D.I. 39, ¶ 41.) As such, SRT acknowledges that MSK retained rights in the patents-in-suit and that SRT does not have “primary responsibility for enforcing” them.

constitutional standing after reviewing the “License Agreement” itself, and not merely the allegations).

B. SRT Lacks Statutory Standing

Title 35 of the United States Code allows a “patentee” to bring a civil action for patent infringement. 35 U.S.C. § 281. The term “patentee” includes the original patentee—whether the inventor or original assignee—and “successors in title.” 35 U.S.C. § 100(d). It does not include “mere licensees.” *Lone Star*, 925 F.3d at 1229 (citing *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1318-19 (Fed. Cir. 2009); *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459 (1926)). Thus, “the critical determination regarding a party’s ability to sue [for infringement] in its own name is whether an agreement transferring patent rights to that party is, in effect, an assignment or a mere license.” *Lone Star*, 925 F.3d at 1229 (internal quotation marks omitted).

In distinguishing between “an assignment” and a “mere license,” the Court must “examine whether the agreement transferred all substantial rights to the patents.” *Id.* (internal quotation marks omitted). This inquiry “depends on the substance of what was granted rather than formalities or magic words.” *Id.* It requires an examination of the “totality” of the agreement “to determine whether a party other than the original patentee has established that it obtained all substantial rights in the patent.” *Id.* The plaintiff has the “burden to provide evidence endowing it with all substantial rights in the patent.” *Fieldturf, Inc. v. Southwest Recreational Indus., Inc.*, 357 F.3d 1266, 1268 (Fed. Cir. 2004).

If a plaintiff fails to do so, it “cannot bring suit in its own name.” *Lone Star*, 925 F.3d at 1229 (citing *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 (Fed. Cir. 2007)). A lawsuit is properly dismissed for such failure “under Rule 12(b)(6) rather than Rule 12(b)(1)” because it is

a statutory defect, rather than a jurisdictional defect like constitutional standing. *Id.* at 1235 (citing *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014)).

In determining whether an agreement transfers all substantial rights to confer statutory standing, courts have “often focused on two salient rights: enforcement and alienation.” *Id.* at 1232. An agreement that fails to transfer all such rights is insufficient. *Id.* Here, the 2020 Settlement Agreement is silent with respect to both enforcement and alienation, and thus insufficient to create statutory standing. *Fieldturf*, 357 F.3d at 1269 (holding that a license that is “silent” with respect to the licensees’ “right to enforce the patent” is “no more than a bare license” and, thus, “fails to convey all substantial interest” sufficient for statutory “standing”).

Even if SRT had the right to enforce an [REDACTED] against others,¹⁰ SRT would still lack statutory standing: a right to sue for merely “commercial infringement” does not qualify as “all substantial rights.” *See Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 979 (Fed Cir. 2005). Indeed, SRT “does not possess the right to sue for ‘all infringement,’” which is necessary. *Lone Star*, 925 F.3d at 1231 (quoting *Sicom Sys.*, 427 F.3d at 979). Moreover, SRT’s unsupported allegations regarding its purported rights under the 2020 Settlement Agreement (discussed above) do not confer SRT with statutory standing because the allegations are inconsistent with the plain language of the one-sentence license provision. Accordingly, SRT lacks statutory standing to sue.

C. SRT’s Claims Are Barred by the 2020 Settlement Agreement

New York law governs the 2020 Settlement Agreement. (*See* Ex. C, § 6.) Under New York law, a settlement agreement is a contract subject to “general principles of contract law.”

¹⁰ Again, the 2020 Settlement Agreement does not even convey to SRT an [REDACTED] to practice the patents-in-suit. Instead, it is an agreement to [REDACTED] (*Id.* § 2.).

Red Ball Interior Demolition Corp. v. Palmadessa, 173 F.3d 481, 484 (2d Cir. 1999). Federal courts interpreting settlement agreements governed by various state laws consistently hold “it is the burden of the parties entering into a settlement agreement to expressly reserve in the agreement any rights that they wish to maintain beyond the date of the settlement.” *Augustine Med., Inc. v. Progressive Dynamics*, 194 F.3d 1367, 1373 (Fed. Cir. 1999) (stating its decision is “[c]onsistent” with “judicial interpretations of general releases”).

As the Supreme Court stated long ago: “[G]eneral language [in a settlement and release] indicates an intent to make an ending of every matter arising under or by virtue of the contract. If parties intend to leave some things open and unsettled, their intent so to do should be made manifest.” *United States v. William Cramp & Sons Ship & Engine Bldg. Co.*, 206 U.S. 118, 128 (1907). In 1976, the Court of Claims expanded this rule:

The rule for releases is that absent special vitiating circumstances, a general release bars claims based upon events occurring prior to the date of the release. And no exception to this rule should be implied for a claim whose facts were well enough known for the maker of the release to frame a general description of it and request an explicit reservation.

Johnson, Drake & Piper v. United States, 531 F.2d 1037, 1047 (Ct. Cl. 1976) (citations omitted).¹¹ More recently, in 1999, the Federal Circuit held that a settlement agreement with release language that is virtually identical to the releases at issue here precluded a later claim between the parties for patent infringement. *Augustine Med.*, 194 F.3d at 1373.

In *Augustine Medical*, the plaintiff, Augustine, had previously sued the defendant, Prudential, “claiming unfair competition” and other torts, alleging that Prudential made misrepresentations to customers regarding the compatibility of its “convective warming

¹¹ The decisions of the former Court of Claims are “binding as precedent” on the Federal Circuit. *E.g., South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982).

blankets” with products sold by Augustine. *Id.* at 1369. It was “undisputed” that “patent infringement was not part of this [first] lawsuit,” which was ultimately settled. *Id.* The parties’ settlement agreement contained a release that included the following language:

[Augustine] does hereby . . . release and forever discharge [Prudential] from any and all manner of action or actions . . . that [Augustine] and/or its owners . . . *have, have had, or may have* against [Prudential] upon or by reason of or relating to any acts, omissions or statements made by [Prudential] on or before the date of this Settlement Agreement, including, but not limited to, *any and all claims that were or could have been asserted* by [Prudential], in the [present lawsuit] . . .

Id. (emphasis in original).

Two years later, Augustine sued Prudential again, alleging that Prudential’s “convective warming blankets”—*i.e.*, the same goods at issue in the prior lawsuit—侵犯了 Augustine’s patents. Augustine argued that the settlement agreement did not preclude such a claim because the release was allegedly limited to “claims based on [Prudential’s] pre-settlement actions and does not refer to future claims.” *Id.* at 1371. The Federal Circuit rejected this argument, relying on the phrase “may have,” which it held “is necessarily future-oriented.” *Id.* In the context of a settlement agreement, “it implies a *future possibility* of [the plaintiff] having a claim.” *Id.* (emphasis in original).

In response, the plaintiff relied on the phrase that appears later in the release, “on or before the date of this Settlement Agreement,” and argued that the release did not preclude a claim for “post-settlement patent infringement [that] had not yet occurred.” *Id.* The Federal Circuit rejected this argument as well. As the court explained:

Augustine has discharged its ability to sue Progressive not for claims that existed on or before the date of the Settlement Agreement, but for claims *related* to any actions taken by Progressive on or before the date of the Settlement Agreement. Prior to and on the date of the Settlement Agreement, as well as after the date of the Settlement Agreement, Progressive was producing and marketing the

convective warming blankets at issue. Augustine's claims for patent infringement then are undeniably *related to* Progressive's production and marketing of the goods at issue on or before the date of the Settlement Agreement. While Augustine's claims for patent infringement in the present litigation are not directly *based on* Progressive's actions prior to the date of the Settlement Agreement, they are sufficiently *related to* those pre-settlement actions so as to fall within the clear meaning of the language of the agreement

Here, Augustine had clear knowledge at the time of the Settlement Agreement that Progressive was producing and marketing the convective warming blankets at issue in the first suit and the Settlement Agreement, and it was likely obvious that the production and marketing would not cease the instant the Settlement Agreement was signed. Therefore, it was Augustine's responsibility to "ma[k]e manifest" its intent to leave the issue of possible future patent infringement claims open for future resolution. Because Augustine knew that factually a claim would exist after the Settlement Agreement, we can grant "no exception to this rule."

Id. at 1371-73 (emphasis in original) (quoting *William Cramp & Sons Ship & Engine Bldg.*, 206 U.S. at 128).

Here, the 2020 Settlement Agreement includes broad "mutual general releases," including to "unaccrued" claims that "relate to or arise out of," *inter alia*, the "Dispute," defined as "any and all disputes related to the 2005 [License] Agreement, the 2011 [Termination] Agreement, the New York Litigation and the Massachusetts Litigation." (Ex. C at preamble, § 5.) The "Dispute" in the prior litigations among the parties related to the very same bluebird gene therapy treatments that use the BB305 vector, which is at issue in this lawsuit.¹² Before and as of the date of the 2020 Settlement Agreement, bluebird was developing these gene therapy

¹² The Court may take judicial notice of the operative pleadings in these prior litigations, attached as Exs. D and E. *Acierno*, 2005 WL 3134060, at *5-6. Although SRT states in its Second Amended Complaint that Defendant bluebird's BB305 Vector "was not at-issue or disclosed" in the New York and Massachusetts Litigations (D.I. 39, ¶¶ 87-89), this is belied by SRT's own arguments in the prior litigations that concerned bluebird's gene therapies using the BB305 vector and its purported competition with SRT's alleged developmental gene therapy. (See, e.g., Ex. D, ¶¶ 48-55, 169-76, 292-315; Ex. E, ¶¶ 1-3, 33-37, 57-67.)

treatments using the BB305 vector, as SRT has alleged in its amended complaint. (D.I. 39, ¶ 5.) Thus, SRT’s claims for patent infringement are unquestionably related to the “Dispute,” as well as to the 2005 License Agreement and the 2011 Termination Agreement, which are facts that arose on or before the 2020 Settlement Agreement. SRT alleges that “Patent Infringement was not a claim that could have been brought . . . in the Prior State Court Litigation” (D.I. 39, ¶ 80), but this is irrelevant at least because the mutual general release is not limited as such.

Moreover, the 2020 Settlement Agreement also includes a further release from SRT that “fully, finally and forever” releases Defendants from “any and all claims” that SRT “may have, ever had or now has” against them, “for upon or by reason of any cause or thing, from the beginning of the world to the Parties’ execution of” the 2020 Settlement Agreement. (Ex. C, § 5.) SRT alleges that this further release “only” applies to claims that SRT “may have or ever had” from “the beginning of the world to the Parties’ execution of” the 2020 Settlement Agreement. (D.I. 39, ¶ 77). But this is the same flawed argument made by the plaintiff and rejected by the court in *Augustine Medical*. It ignores that the actual language of the release in the 2020 Settlement Agreement applies to, *inter alia*, claims that SRT “may have” against Defendants in the future, “for upon or by reason of any cause or thing, from the beginning of the world to the Parties’ execution of” the 2020 Settlement Agreement. (Ex. C, § 5.)

As SRT’s own allegations in the New York Litigation make plain, the gene therapy treatments at issue in this lawsuit are such a “cause or thing” that existed before the 2020 Settlement Agreement. For example, SRT alleged in the New York Litigation: (1) “[b]luebird is built primarily around development of gene therapy for thalassemia and sickle cell diseases;” Ex. D, ¶ 169; (2) “[b]luebird was aware that the [SRT] Vector of its competitor, [SRT], was better than its own product,” *id.*, ¶ 293; (3) “[b]luebird had the ability to incorporate all of

[SRT's] Intellectual Property into the Bluebird vector," *id.*, ¶ 295; and (4) "[b]luebird developed its own vector, incorporating the [SRT] Intellectual Property and palmed off the vector as its own product," *id.*, ¶ 302.

Accordingly, SRT had clear knowledge at the time of the 2020 Settlement Agreement that bluebird was developing its gene therapy treatments using a lentiviral vector. It was therefore SRT's responsibility to "make manifest" its intent to leave the issue of possible future patent infringement claims, based on such development, open for future resolution. *Augustine Med.*, 194 F.3d at 1373 (internal quotations omitted). SRT did not do so. SRT now alleges that it "did not have an exclusive commercial license" to the Patents-in-Suit before the execution of the Settlement Agreement (D.I. 39, ¶ 81), but this is irrelevant. SRT obtained the rights upon which it now relies in the very same legal instrument where it provided broad releases to Defendants, *i.e.*, the 2020 Settlement Agreement. Thus, even accepting as true SRT's allegations that it received through the 2020 Settlement Agreement a right to sue for infringement, SRT simultaneously released that right, with respect to Defendants, in the very same document.

Finally, MSK/SKI, as the assignee and licensor of the patents-in-suit, also provided broad releases to Defendants in the 2020 Settlement Agreement.¹³ SRT can hardly contend that it received license rights to pursue infringement claims against Defendants that MSK/SKI released pursuant to the very same document that allegedly provides SRT its license rights. In fact,

¹³ Although SRT recognizes that the 2020 Settlement Agreement resolved the Massachusetts Litigation against Defendant Third Rock, SRT states that "Third Rock was not a party to the [2020] Settlement Agreement." (D.I. 39, ¶ 78.) Defendant Third Rock, however, was a released party in the 2020 Settlement Agreement as a "past . . . shareholder[]" of bluebird. (Ex. C, § 5.) Further, even if Third Rock was not released (which it was), SRT still could not sue it for indirect infringement because the alleged direct infringer (bluebird) was released from liability. *See, e.g., Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 925 (2014) ("[T]he nature of the rights created by the Patent Act defeats the notion that Congress could have intended to permit inducement liability where there is no underlying direct infringement.").

MSK/SKI agrees that SRT’s infringement claims in this action are “improper” in light of the releases granted to Defendants in the 2020 Settlement Agreement. (*See* Ex. F.) Accordingly, the Court should dismiss SRT’s claims with prejudice as barred by the 2020 Settlement Agreement.

D. Alternatively, Arbitration Should Be Compelled and the Proceedings Should Be Stayed

The FAA provides:

A written provision in any . . . contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract . . . or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract [or] transaction . . . shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.

9 U.S.C. § 2. Section 3 of the FAA provides that, if any suit is brought “upon any issue referable to arbitration,” the court “shall on application of one of the parties stay the trial of the action until such arbitration has been had in accordance with the terms of the agreement.” *Id.* § 3. Section 4 of the FAA authorizes parties aggrieved by failures to arbitrate to petition the courts for orders compelling arbitration. *See id.* § 4.

Congress enacted the FAA to promote “a liberal federal policy favoring arbitration.” *Moses H. Cone Mem’l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24 (1983). Where there exists a valid agreement to arbitrate and a dispute falls within its scope, the FAA “leaves no place for the exercise of discretion by a district court, but instead mandates that district courts shall direct the parties to proceed to arbitration.” *Dean Witter Reynolds, Inc. v. Byrd*, 470 U.S. 213, 218 (1985) (emphasis in original). The party seeking to avoid arbitration “bears the burden of proving that the claims at issue are unsuitable for arbitration.” *Green Tree Fin. Corp. v. Randolph*, 531 U.S. 79, 91 (2000). Moreover, a motion to compel arbitration “should not be denied unless it may be said with positive assurance that the arbitration clause is not susceptible

of an interpretation that covers the asserted dispute.” *AT&T Techs., Inc. v. Commc’ns Workers of Am.*, 475 U.S. 643, 650 (1986).

Here, the parties agreed to a broad arbitration agreement in Section 7 of the 2020 Settlement Agreement. It makes arbitrable “any dispute concerning” the 2020 Settlement Agreement, “its construction, or its actual or alleged breach.” (Ex. C, § 7.) It specifies that such arbitration shall be conducted before Mr. Ichel, if available, and references the AAA Arbitration rules and a tribunal seated in New York. (*Id.*)

SRT alleges in its Second Amended Complaint that “[t]he Dispute Resolution provision in the [2020] Settlement Agreement does not apply” because “this dispute between [SRT] and Bluebird does not concern any actual or alleged breach of the Settlement Agreement.” (D.I. 39, ¶ 82 (citing D.I. 16, Ex. D, ¶ 7).) This allegation ignores that the parties agreed to arbitrate any dispute regarding “the construction” of the 2020 Settlement Agreement. As demonstrated herein, the construction of the 2020 Settlement Agreement bears on whether SRT has standing (which it does not), and whether it has released its claims (which it has). Accordingly, if the Court does not dismiss this case outright, and if SRT raises a legitimate dispute regarding the construction of its license rights or the releases under the 2020 Settlement Agreement, the Court should stay this case and compel arbitration to address threshold issues.

V. CONCLUSION

Defendants respectfully request an order dismissing this action with prejudice. In the alternative, Defendants respectfully request an order staying these proceedings and compelling arbitration to address any threshold issues applicable to SRT’s alleged standing pursuant to the 2020 Settlement Agreement, and the broad releases therein.

Dated: April 6, 2022

/s/ Jeremy A. Tigan

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CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 6, 2022, upon the following in the manner indicated:

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